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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,011	10/31/2005	Nava Zisapel	2007-122	9212

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EXAMINER
KIM, JENNIFER M

ART UNIT	PAPER NUMBER
1628	

NOTIFICATION DATE	DELIVERY MODE
12/18/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/555,011	ZISAPEL ET AL.	
	Examiner	Art Unit	
	JENNIFER M. KIM	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *September 14, 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed September 14, 2009 have been received and entered into the application.

Response to Arguments

Applicants' arguments filed September 14, 2009 have been fully considered but they are not persuasive. Applicants argue that the Declaration by Dr. Moshe Laudon explains that the effects of melatonin administration can vary significantly depending on such factors as the time of day at which it is administered, the amount administered and the identity of any other pharmacological agents that the patient is taking. Further, it is highly inaccurate to assert, on the basis of the statement in the Oxenkrug et al patient that melatonin improves cognition. The Declaration by Dr. Moshe Laudon has been carefully reviewed and considered. However, it is not persuasive because Oxenkrug et al clearly teach and illustrate by their example, that melatonin improve cognition and protect against neurotoxicity. Further, Applicants attention is drawn to Jean-Louis et al. (1998), which also teach that melatonin effects on cognition in elderly with mild cognitive impairment. The Jean-Louis et al in their experimental data suggest that melatonin can safely improve memory in cognitive impairment in elderly. Moreover, the references employed in the Declaration were not considered since they are not on record.

Applicants argue that the disclosure in the cites references do not suggest that melatonin can be administered to a subject who is receiving nicotine or a nicotine receptor agonist as nicotine replacement therapy to treat impairment of sleep quality, impairment of cognition or impairment of memory in a subject which is an adverse effect of tobacco withdrawal. This is not found persuasive because, it is noted that the features upon which applicant relies (i.e., an adverse effect of **tobacco withdrawal**) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In this case, the recited limitation of the phrase “nicotine replacement therapy" has been examined by given its broadest and reasonable interpretation. Myer teaches that it is well known that nicotine increases cognition and humans. Therefore, one of ordinary skill in the art would recognize that the nicotine can be "replaced" which encompasses the meaning of "put back in a previous place or position" to treat cognition as taught by Myer. Further, to incorporate melatonin to nicotine cognition therapy taught by Myer et al is obvious because such incorporation would beneficially achieve at least an additive cognitive effect. In this case, it would have been *prima facie* obvious to combine melatonin and nicotine conjointly in a formulation to treat cognitive or memory impairment.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 22-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers et al. (U.S.Patent No. 6,486,172 B2) and Oxenkrug et al. (U.S. Patent No. 6,353,015 B1).

Myers et al. teach nicotine increase cognition and attention. (column 17, lines 30-34).

Oxenkrug et al. teach melatonin improve cognition and protect against neurotoxicity. (column 12, lines 20-25).

The claims differ from the cited references in claiming combination of nicotine and melatonin to treat cognition and memory impairment. To employ combinations of nicotine and melatonin to treat cognition and memory impairment would have been obvious because all the components are well known individually for treating cognition and memory impairment. It would be expected that the combination of components would treat cognition and memory impairment conditions as well.

One of ordinary skill in the art would have combined the nicotine and melatonin by known methods and that in combination, each element merely would have performed

the same cognition and memory impairment activity as it did separately. The convenience of putting the compounds having the same cognition and memory impairment activity of nicotine and melatonin together in one dosage form, though perhaps a matter of great convenience does not produce a "new" or "different" function and to those skilled in the art, the use of the old elements in combination would have been obvious. The motivation for combining the components flows from their individually known common utility (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). Regarding the kit of instant claims 37-42, it is a standard of practice in the pharmaceutical arts to enclose a composition in a vessel, and to enclose instructions for use in a package. The amounts of active agents to be used, the dosing schedule e.g. prior to bed time, the pharmaceutical forms, e.g., tablets, controlled sustained release formulations, depot etc; mode of administration such as rectal or oral; flavors, surfactant or diluents are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations and modes of administration.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/
Primary Examiner, Art Unit 1628

Jmk
December 9, 2009